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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/281,430	03/30/1999	INDU PARIKH	121-160	7226

7590 06/25/2002

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EXAMINER	
WARE, TODD	
ART UNIT	PAPER NUMBER

1615

DATE MAILED: 06/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/281,430	PARIKH ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Todd D Ware	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 April 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 26-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 26-38 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

Receipt of request for extension of time (granted) and amendment filed 4-1-02 is acknowledged. Claims 8-12, 14, 17-20, and 22-25 have been canceled and new claims 26-38 have been added. In view of the new grounds for rejection, this action is "non-final."

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

a. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 26-33, 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,342,625; hereafter '625) in view of Hamied et al (5,929,030; hereafter '030) or vice versa.

'625 teaches a non-aqueous, microemulsion pre-concentrate composition comprising a hydrophobic or water insoluble agent such as cyclosporin, 10 to 80% of a hydrophobic component (C 8, L 58- C 9, L39 and examples), 20 to 80% of a surfactant phase (C 9, L 40- C 12, L 6 and examples) and a hydrophilic component, such as ethanol and/or 1,2 propylene glycol. '625 teaches that the particle size of the microemulsions obtainable from the pre-concentrate is about 150-2000 Å (15-200 nm) when added to water.

'030 microemulsion formulations for water insoluble active substances such as taxol, 20-80% of a hydrophobic oil phase, 1-60% of a surfactant phase, and 15-75% of a hydrophilic phase.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '625 and '030 with the motivation of enhancing the resorption/bioavailability of taxol and the expectation that microemulsions provide increased resorption/bioavailability over non-microemulsion formulations, as taught by '625. Furthermore, motivation is also provided in '030 which teaches that such compositions do not form solid microfine active agent after administration. Thus, the expectation is that such a formulation would not precipitate taxol after administration.

3. Claims 26-33, 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,342,625; hereafter '625) in combination with Hamied et al (5,929,030; hereafter '030) and further in combination with Rathi et al (6,004,573; hereafter '573) or Hamied et al (5,929,030; hereafter '030) in combination with Hauser et al (5,342,625; hereafter '625) and further in combination with Rathi et al (6,004,573; hereafter '573).

'625 and '030 are relied upon for all that they teach as stated previously.

'573 is relied upon to further reinforcing the similar dissolution properties of cyclosporin and taxol, stating that they are both hydrophobic agents.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '625 and '030 with the motivation of enhancing the

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resorption/bioavailability of taxol and the expectation that microemulsions provide increased resorption/bioavailability over non-microemulsion formulations, as taught by '625, for hydrophobic active agents. Furthermore, motivation is also provided in '030 which teaches that such compositions do not form solid microfine active agent after administration. Thus, the expectation is that such a formulation would not precipitate hydrophobic active agent such as taxol after administration.

4. Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,342,625; hereafter '625) in combination with Hamied et al (5,929,030; hereafter '030) and further in combination with Sime et al (WO 96/35415; hereafter '415).or Hamied et al (5,929,030; hereafter '030) in combination with Hauser et al (5,342,625; hereafter '625) and further in combination with Sime et al (WO 96/35415; hereafter '415).

'625 and '030 are relied upon for all that they teach as stated previously.

'415 is relied upon for teaching compositions comprising grapefruit extract and taxol to inhibit cytochrome P450 enzyme and decrease metabolism/increasing stability of the taxol.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include grapefruit extract in a taxol microemulsion with the motivation of decreasing metabolism/increasing stability of the taxol.

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5. Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,342,625; hereafter '625) in combination with Hamied et al (5,929,030; hereafter '030) in combination with Rathi et al (6,004,573; hereafter '573) and further in combination with Sime et al (WO 96/35415; hereafter '415) or Hamied et al (5,929,030; hereafter '030) in combination with Hauser et al (5,342,625; hereafter '625) in combination with Rathi et al (6,004,573; hereafter '573) and further in combination with Sime et al (WO 96/35415; hereafter '415).

'625, '030 , and '573 are relied upon for all that they teach as stated previously.

'415 is relied upon for teaching compositions comprising grapefruit extract and taxol to inhibit cytochrome P450 enzyme and decrease metabolism/increasing stability of the taxol.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include grapefruit extract in a taxol microemulsion with the motivation of decreasing metabolism/increasing stability of the taxol.

#### ***Response to Arguments***

6. Applicant's arguments with respect to the instant claims have been considered but are moot in view of the new ground(s) of rejection. It is noted that applicant has argued the structural differences between cyclosporin and taxol, however the rejection is based upon the hydrophobicity/water-insoluble characteristics of these active agents.

***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
June 20, 2002

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
